REMARKS

Favorable reconsideration is respectfully requested in view of the above amendments and following remarks. Claims 30 and 31 have been amended editorially. Claim 32 is new, and is supported by page 38, lines 17-29 of the present specification. No new matter has been added. Claims 15, 17 and 30-31 are pending.

Claims 15, 17, 30 and 31 are rejected under 35 USC 112, second paragraph, as being indefinite. Claim 30 is directed to a method of diagnosing a condition in a subject using a molecular marker, the molecular marker being histamine releasing factor (HRF) protein. Claim 30 recites that an increase in the amount of HRF protein in the sample from the subject as compared to the amount of HRP protein in the normal control indicates that the subject has the condition. Claim 30 further recites that a disease caused by endometriosis is dysmenorrhea, infertility or adenomyosis uteri. Claim 30 also recites "normal control." Accordingly, Applicants submit that claim 30 and its dependent claims are definite.

Claims 15, 17, 30 and 31 are rejected under 35 USC 102(b) as being anticipated by Hochstrasser et al. (WO 94/12881). Applicants respectfully traverse the rejection.

Claim 1 is directed to a method of diagnosing a condition in a subject using a molecular marker, the molecular marker being histamine releasing factor (HRF) protein. Claim 30 recites measuring an amount of HRF protein in a sample from the subject, comparing the amount of HRF protein in the sample from the subject with an amount of HRF protein in a normal control, and determining if the subject has the condition based on the comparison. Claim 30 further recite that an increase in the amount of HRF protein in the sample from the subject as compared to the amount of HRF protein in the normal control indicates that the subject has the condition, the condition being (1) endometriosis, (2) a disease caused by endometriosis, or (3) a risk for endometriosis or a disease caused by endometriosis, the disease caused by endometriosis being dysmenorrhea, infertility or adenomyosis uteri.

Hochstrasser is directed to a method of detecting a cancerous condition in a human using a molecular marker, the molecular marker being translationally controlled tumor protein p21 (TCTPp21). Hochstrasser teaches removing a clinical sample from the human, detecting the level of TCTPp21 in the sample and then determining if the level of

TCTPp21 is greater than the level of TCTPp21 in a normal sample. Hochstrasser indicates that method is useful in cancer in general, including breast, lung, ovarian, cervical, prostate and colon cancer. However, even accepting arguendo that Hochstrasser's TCTPp21 corresponds to the HRF protein of claim 30, the reference is silent as to whether an increase in the amount of the TCTPp21 in the sample from the subject as compared to the amount of HRF protein in the normal control indicates that the subject has the condition, the condition being (1) endometriosis, (2) a disease caused by endometriosis, or (3) a risk for endometriosis or a disease caused by endometriosis, the disease caused by endometriosis being dysmenorrhea, infertility or adenomyosis uteri.

On the other hand, claim 30 involves the use of HRF protein as a molecular marker for determining if the subject has the condition, the condition being (1) endometriosis, (2) a disease caused by endometriosis, or (3) a risk for endometriosis or a disease caused by endometriosis, the disease caused by endometriosis being dysmenorrhea, infertility or adenomyosis uteri, as opposed to cancer in general. Hochstrasser fails to provide any guidance or experimental data to show that HRF protein could be used as a molecular marker to diagnose the condition as required by claim 30. Accordingly, claim 30 is patentable over the reference.

Claim 17 is rejected under 35 USC 112, first paragraph, as failing to comply with the written description requirement. The discussion at page 19, lines 3-30 indicates that a variety of mutant HRF polynucleotides are known, such as SEQ ID NO: 1, the translated sequence being SEQ ID NO: 2. The discussion at page 19 beginning on line 13 indicates that, based on the well characterized HRF gene/amino acid sequence of SEQ ID NO: 1, domains can be inserted into known expression vector systems by known methods so as to generate an antibody specific for HRF protein. The discussion at page 5, lines 20-23 in particular indicates that a peptide containing a sequence of 5 to 20 amino acid residues selected from the amino acid sequence at positions 90 to 130 of SEQ ID NO: 2 can be used, and at page 38, lines 17-29, a working example is provided (an example of an antibody generated from a peptide containing a 16 amino acid residue peptide at positions 101 to 116 of SEQ ID NO: 2 is provided). Thus, in view of how well the HRF protein sequence is characterized in the art, the discussion of suitable processes for obtaining the antibodies for the HRF protein in the present specification adequately shows that the

Applicants were in possession of the variety of antibodies that can be produced from the peptide as required by claim 17.

New claim 32 is patentable over the reference for at least the same reasons as claim 30.

Favorable reconsideration in the form of a notice of allowance is respectfully requested. Any questions regarding this communication can be directed to the undersigned attorney, Douglas P. Mueller, Reg. No. 30,300, at (612) 455-3804.

Respectfully submitted,

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